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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	066654-0515	8259
41552 7590 01/29/2008 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Hong Sang

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 16, 20-27, 32-34, 36, 44, 50-69, 71-81 and 83-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 16, 20-27, 32-34, 36, 44, 50-69, 71-81 and 83-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Reed

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

2. Claims 11-13, 16, 20-27, 32-34, 36, 44, 50-69, 71-81, and 83-99 are pending. Claims 1-10, 14, 15, 17-19, 28-31, 35, 37-43, 45-49, 70 and 82 are cancelled.

3. Claims 11-13, 16, 20-27, 32-34, 36, 44, 50-69, 71-81, and 83-99 are under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on 10/31/2007 has been considered. A signed copy is attached hereto.

Objections Withdrawn

5. The objection to claims 70 and 82 is withdrawn in view of applicant's cancellation of the claims.

Response to Arguments

Claim Rejections - 35 USC § 102

6. The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 102(b) as being anticipated by Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) is maintained.

The response states that the claims are directed to methods that include determining the level of BAG-1 expression in stage I of breast cancer. Turner et al. does not teach or suggest BAG-1 expression in stage I of breast cancer, or stage II of breast cancer with no lymph node involvement.

Applicants' arguments have been carefully considered but are not found persuasive. Turner et al. determined the expression of BAG-1 in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast in 87 breast cancer patients (see abstract lines 3-5), of which 82 patients have IC and 5 patients have pure DCIS (see abstract lines 6-7). Turner et al. teach the slides were rated on a scale of intensity and % distribution within the BBE, DCIS and IC components (see lines 8-9). Turner et al. teach that the patients had a median follow-up of 13 years. Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. The instant specification teaches that stage I of breast cancer requires no lymph node involvement, and stage II of breast cancer involves either no lymph node involvement and a large primary tumor or initial lymph node involvement and a small

primary tumor (see specification, page 25, lines 17-22). Because DCIS is a breast cancer with no lymph node involvement, the DCIS reads on the instant stage I, and stage II with no lymph node involvement. Therefore, Turner et al. teach all limitations of the claims.

Claim Rejections - 35 USC § 103

7. The rejection of claims 11-13, 16, 20-22, 24-27, 32-34, 36, 44, 50-61, 67-69, 71-73, 75-81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sano et al. (US patent NO. 5665539) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Sano et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sano et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 6). Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Sano et al.

8. The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-68, 71-73, 75-79, 81, 83-99 under 35 U.S.C. 103(a) as being unpatentable over Turner et al.

(Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sauter et al. (British Journal of Cancer, 1997, 76(4): 494-501) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Sauter et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sauter et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 6). Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Sauter.

9. The rejection of claims 11, 13, 16, 20-27, 32, 34, 36, 44, 50-61, 67, 68, 71-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Takayama et al. (Cancer Res. 1998, 58: 3116-3131, IDS) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Takayama et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Takayama et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 (see paragraph 6). Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Takayama.

10. Claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-68, 71-73, 75-79, 81, and 83-99 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Love (US Patent No. 6,221,622B1, Data of Patent 4/24/2001, earliest effective filing date 4/28/1998).

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Love does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Love.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, 67, 68, 71-73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97 and 98 (see paragraph 6). Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Love.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang

Hong Sang, Ph.D.
Art Unit 1643
1/11/2008